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K110319

APR 14 2011

510(k) Summary

EverCross™ .035" OTW PTA Dilatation Catheter

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.

1. Submitter Information

Applicant	ev3 Inc. 3033 Campus Drive Plymouth, MN 55441-2651 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Paula Cordero, RAC Manager, Regulatory Affairs
Date Prepared	March 8th , 2011

2. Device Information

Device Trade Name	EverCross™ .035" OTW PTA Dilatation Catheter
Device Common Name	PTA Dilatation Catheter
Classification Name	21 CFR 870.1250- Percutaneous Catheter Product Code: LIT - Catheter, Angioplasty, Peripheral, Transluminal DQY- Catheter, Percutaneous
Classification Panel	Cardiovascular

3. Predicate Devices

Device Trade Name	EverCross™ .035" OTW PTA Dilatation Catheter
510(k) Number	K082579, K103322
510(k) Clearance Date	November 20, 2008, December 6th, 2010

4. Device Description The EverCross Peripheral Dilatation Catheter is an over the wire (OTW) 0.035" dual lumen catheter with a distally mounted semi-compliant inflatable balloon and a flush cut tip to aid in crossing tight

stenoses. The distal portion of the catheter shaft has a hydrophilic coating for lubricity. The catheter manifold includes two lumens. The lumen marked "THRU" is the central lumen of the catheter which terminates at the distal tip. This lumen is used to pass the catheter over a guidewire with a maximum outer diameter of 0.035 inches. The lumen, marked "BALLOON" is used to inflate and deflate the dilatation balloon with a solution of contrast medium and saline. The balloon has two radiopaque markers for positioning the balloon relative to the stenosis.

The EverCross .035" OTW Dilatation Catheter uses the following materials: Nylon 12, Nylon/Pebax, Platinum/Iridium alloy, Thermoplastic Polyester Elastomer, Polycarbonate, hydrophilic coating.

5. Indications for Use

The EverCross .035" OTW PTA Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

6. Comparison of Technological Characteristics- Add more detail-

The EverCross PTA Dilatation Catheter has the following similarities to the predicate device:

- Identical intended use
- Identical indications for use
- Identical indication for post stent dilatation
- Identical materials
- Identical operating principle

The differences include addition of 10x20mm and 12x20mm balloon sizes, a balloon design modification, a change from bevel-cut tip to flush-cut tip and a stronger monolumen. Design verification testing was performed to demonstrate the proposed devices met acceptance criteria identical to or based on predicate device acceptance criteria.

7. Performance Testing Summary

To demonstrate substantial equivalence of the proposed device, to the predicate device, the technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Analysis procedures, the following in vitro tests were performed:

- Balloon Outer Diameter at Operating Pressure
- Balloon Length
- Balloon Compliance
- Balloon Burst Strength
- Balloon Fatigue

In-vitro and in-vivo testing was completed on the predicate device to

support a determination of substantial equivalence. Testing included dimensional, performance, radiopacity, coating integrity and durability, biocompatibility, packaging, shelf-life and sterilization. Test results met the specified acceptance criteria and were included in K082579 and K103322.

The results from these tests demonstrate that the technological characteristics and performance criteria of the EverCross .035" OTW PTA Dilatation Catheter are comparable to the predicate device and performs in a manner equivalent to the predicate device currently on the market for the same intended use.

8. Conclusions

Based on the intended use, technological characteristics, safety and performance testing included in this submission and in previously cleared submissions for this product, ev3 considers the EverCross .035" OTW PTA Dilatation Catheter to be substantially equivalent to the predicate device EverCross .035" OTW PTA Dilatation Catheter (K082579, K103322).

Indications for Use Statement

510(k) Number (if known): _____

Device Name: EverCross™ .035" OTW PTA Dilatation Catheter

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ev3, Inc.
c/o Paula Cordero, RAC
Manager, Global Regulatory Affairs
3033 Campus Drive
Plymouth, MN 55441

APR 14 2011

Re: K110319
Trade/Device Name: EverCross™ 0.035" OTW PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: April 08, 2011
Received: April 11, 2011

Dear Ms. Cordero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110319

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110319